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HOUSE OF COMMONS SESSION 1999–2000

# SCIENCE AND TECHNOLOGY COMMITTEE

## Third Report

# SCIENTIFIC ADVISORY SYSTEM: DIABETES AND DRIVING LICENCES

## Volume I

## Report and Proceedings of the Committee

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*Ordered by* The House of Commons *to be printed*
*9 February 2000*

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HOUSE OF COMMONS SESSION 1999–2000

# SCIENCE AND TECHNOLOGY COMMITTEE

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## Third Report

# SCIENTIFIC ADVISORY SYSTEM: DIABETES AND DRIVING LICENCES

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## The Science and Technology Committee

The Science and Technology Committee is appointed to examine on behalf of the House of Commons the expenditure, administration and policy of the Office of Science and Technology (and any associated public bodies). Its constitution and powers are set out in House of Commons Standing Order No. 152.

The Committee has a maximum of eleven members, of whom the quorum for any formal proceedings is three. The members of the Committee are appointed by the House and unless discharged remain on the Committee until the next dissolution of Parliament. The present membership of the Committee is as follows:[1]

Dr Michael Clark MP *(Conservative, Rayleigh)*[2]
Mr Nigel Beard MP (*Labour, Bexleyheath and Crayford*)[2]
Mrs Claire Curtis-Thomas MP (*Labour, Crosby*)[2]
Dr Ian Gibson MP (*Labour, Norwich North*)[2]
Mr Robert Jackson MP (*Conservative, Wantage*)[3]
Dr Lynne Jones MP (*Labour, Birmingham Selly Oak*)[2]
Mr Nigel Jones MP (*Liberal Democrat, Cheltenham*)[2]
Dr Ashok Kumar MP (*Labour, Middlesborough South and East Cleveland*)[2]
Mr Ian Taylor MP (*Conservative, Esher and Walton*)[4]
Dr Desmond Turner MP (*Labour, Brighton Kemptown*)[2]
Dr Alan W Williams MP (*Labour, Carmarthen East and Dinefwr*)[2]

On 30 July 1997, the Committee elected Dr Michael Clark as its Chairman.

The Committee has the power to require the submission of written evidence and documents, to examine witnesses, and to make Reports to the House. In the footnotes to this Report, references to oral evidence are indicated by 'Q' followed by the question number, references to the written evidence are indicated by 'Ev' followed by a page number.

The Committee may meet at any time (except when Parliament is prorogued or dissolved) and at any place within the United Kingdom. The Committee may meet concurrently with other committees or sub-committees established under Standing Order No. 152 and with the House's European Scrutiny Committee (or any of its sub-committees) for the purpose of deliberating, taking evidence or considering draft reports. The Committee may exchange documents and evidence with any of these committees, as well as with the House's Public Accounts, Deregulation and Environmental Audit Committees.

The Reports and evidence of the Committee are published by The Stationery Office by Order of the House. All publications of the Committee (including press notices) are on the Internet at www.parliament.uk/commons/selcom/s&thome.htm. A list of Reports of the Committee in the present Parliament is at the end of this volume.

All correspondence should be addressed to The Clerk of the Science and Technology Committee, Committee Office, House of Commons, London SW1A 0AA. The telephone number for general inquiries is: 020 7219 2794; the Committee's e-mail address is: scitechcom@parliament.uk.

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[1] Mrs Caroline Spelman MP (*Conservative, Meriden*) was appointed on 14 July 1997 and discharged on 22 June 1998
Mr David Atkinson MP (*Conservative, Bournemouth*) was appointed on 14 July 1997 and discharged on 30 November 1998.
Mrs Jacqui Lait MP (*Conservative, Beckenham*) was appointed on 22 June 1998 and discharged on 5 July 1999.

[2] Appointed on 14 July 1997.

[3] Appointed on 5 July 1999.

[4] Appointed on 30 November 1998.

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## SUMMARY OF RECOMMENDATIONS AND CONCLUSIONS

**(a) The UK's position on exceptional cases for renewing existing professional insulin-treated drivers' entitlements was to some extent based on the view of the Honorary Advisory Panel. That panel's view, however, was influenced by DETR advice that other member states were applying a ban. The DETR now concedes that "that information turned out not to be accurate". We recommend that the Government refers this matter back to the Honorary Advisory Panel for further consideration based on an understanding of practice in other EU countries (paragraph 22).**

**(b) We find the rules for medium-sized vehicles as they apply to insulin-treated drivers illogical and inconsistent. We see no reason why the exception for voluntary drivers of minibuses should be extended to those who do not meet the required medical standards for driving larger vehicles (paragraph 23).**

**(c) We consider that the exception for insulin-treated professional drivers of small lorries has been applied in an unacceptably arbitrary manner. We recommend that the overriding criterion which should be applied in determining whether or not any diabetic driver should obtain a Group II licence should be the risk of the driver being unaware of the onset of hypoglycaemia (paragraph 24).**

**(d) We welcome the planned campaign to raise awareness of the need to declare medical conditions which may affect driving (paragraph 25).**

**(e) We recommend that clear terms of reference be drawn up for the Honorary Advisory Panel, setting out precisely its role in advising Ministers, the limits on the areas it should advise upon and the split between Panel, official and Ministerial responsibility (paragraph 26).**

**(f) The current members of the Honorary Advisory Panel have the necessary expertise and experience in diabetes and insulin-induced hypoglycaemia (paragraph 27).**

**(g) We recommend that the Government appoints an expert on road traffic accident statistics to the Honorary Advisory Panel on Driving and Diabetes Mellitus and considers similar appointments to the other Honorary Medical Advisory Panels (paragraph 28).**

**(h) The absence of lay membership on the Honorary Advisory Panel is unsatisfactory. We recommend that the Government appoints two lay members to this Panel and considers similar action in respect of the other Honorary Medical Advisory Panels (paragraph 29).**

**(i) We recommend that the Government and the British Diabetic Association jointly identify an insulin-treated diabetic to attend meetings of the Honorary Advisory Panel as a non-voting member. While such an individual should not be a formal member of the Panel, he or she should have full access to Panel papers and be invited to participate fully in discussions (paragraph 30).**

**(j) The arrangements for appointment of members to Honorary Medical Advisory Panels are unsatisfactory. We recommend that the Government establish a fixed term of appointment of no longer than five years, which should be renewable only once. Such a policy, although necessary to comply with the rules of the Commissioner for Public Appointments, should be implemented gradually so that continuity is maintained and to ensure that there is no large change in the Panel's membership at any one time (paragraph 31).**

**(k) We recommend that the Honorary Advisory Panel publishes an annual report and, shortly afterwards, hold an annual meeting with the British Diabetic Association and other interested parties to discuss matters of common interest and to explain any complex recommendations made (paragraph 32).**

**(l) We recommend that the Honorary Advisory Panel's agendas are published in advance of meetings and that minutes be published shortly after meetings, with the privacy of any individuals discussed suitably protected (paragraph 33).**

**(m) We recommend that the Government makes explicit the risk basis for road safety policy in respect of licensing of individuals with medical conditions which potentially affect fitness to drive (paragraph 35).**

**(n) The DETR states that independent UK evidence is unnecessary because the present policy and practices are derived from obligations to adhere to European legislation based on "long-standing expert assessment of the dangers associated with the driving of larger vehicles by insulin-treated diabetics". This assessment does not appear to be supported by any evidence. We recommend that the evidence basis for such expert assessment should be made publicly available (paragraph 38).**

**(o) We recommend that the scope and depth of the Fitness to Drive Research Programme should be enhanced and adequately funded (paragraph 39).**

**(p) We recommend that the Government reviews policy in the area of licensing procedures for insulin-treated diabetic drivers of Group II vehicles including an analysis of the feasibility of implementing the British Diabetic Association proposals for individual assessment (paragraph 41).**

# THIRD REPORT

The Science and Technology Committee has agreed to the following Report:—

## SCIENTIFIC ADVISORY SYSTEM: DIABETES AND DRIVING LICENCES

## CHAPTER ONE: INTRODUCTION

1. The Chief Scientific Adviser to the Government, Sir Robert May, has stated that "Science is playing an increasingly influential role in contributing to the formulation both of UK and international ... policy and regulatory decisions".[1] Scientific advice is used to underpin Government policy and decision-making in a broad range of fields, particularly those which relate not only to health, public safety, and environmental protection but also to other policy areas such as transport. Government needs to ensure that the mechanisms which it has in place can provide timely and effective scientific advice. The scientific advisory system must identify and define the issues and equip Government with the means to make well-informed decisions in matters of public policy and to communicate reliable information to the public about the associated risks and uncertainties.

2. We decided to conduct our inquiry into The Scientific Advisory System by carrying out a number of case studies. This is the third case study in our inquiry into The Scientific Advisory System and how it assists the Government in making well-informed decisions and developing sustainable policies, taking into account a full range of scientific evidence. The previous two case studies examined the scientific advisory system and its relevance to genetically modified foods and mobile phones.[2]

### Driving and Road Safety

3. Driving has come to be widely held as an important and valued freedom. Some 30 million people in the UK hold driving licences.[3] Driving provides personal mobility and independence and for many is an important part of daily life for both work and leisure. For some, driving is a necessary, integral part of their employment. To take away an individual's right to drive is regarded by many as a serious restriction and something which should only be done when the individual poses real risk to themselves or others.

4. With the right to drive comes the responsibility to drive safely, thus protecting passengers and other road users. There is no doubt that there are some medical conditions which make an individual unfit to drive. It is entirely reasonable that driving restrictions or even complete bans be placed on individuals with conditions known to pose a significant road safety risk. The Department of the Environment, Transport and the Regions (DETR) obtains scientific advice on such matters from its Honorary Medical Advisory Panels, each of which is set up to advise on particular conditions, in order to determine those medical conditions which represent an unacceptable safety risk when driving.[4] In this case study we have chosen one medical condition — insulin-treated diabetes mellitus[5] — to examine the Government's use of scientific advice in determining policy and practice in respect of medical fitness to drive.

### Conduct of the Inquiry

5. During this case study we have received evidence from a range of organisations and individuals. In two oral evidence sessions we have heard from three sets of witnesses. Their expertise and insights have been supplemented by 11 written submissions. We are grateful to those who have assisted us during our inquiry either through oral or written evidence.

---

[1] Sir Robert May, *The Use of Scientific Advice in Policy Making*, March 1997, p.1.

[2] First Report, Session 1998-99, *Scientific Advisory System: Genetically Modified Foods*, HC 286 and Third Report, Session 1998-99, *Scientific Advisory System: Mobile Phones and Health*, HC 489.

[3] Ev. p. 44.

[4] Ev. p. 69.

[5] Hereafter "*diabetes*".

6. We would also like to thank our specialist advisers for this case study: Professor Derek Burke, former Vice-Chancellor of the University of East Anglia, and Professor Michael Elves, former Director of the Office of Scientific and Educational Affairs, Glaxo Wellcome plc.

## Diabetes, Insulin and Hypoglycaemia

7. Insulin is required by the body to regulate glucose levels in blood and tissue. Insulin is normally produced by the body in response to increases in blood glucose concentrations caused by eating and causes blood glucose to fall, but people with diabetes produce little or no insulin or fail to respond normally to insulin. Diabetes affects more than 1.4 million individuals in the UK.[6] Of these, more than 10% need to treat their condition by injecting insulin, typically twice each day, in order to control their blood glucose.[7] Others, with a milder form of diabetes may regulate it through a controlled diet or by taking tablets.

8. One potential side-effect of injecting insulin is hypoglycaemia which results when the insulin causes the blood sugar to fall seriously below normal.[8] Hypoglycaemia can lead to abnormal or irrational behaviour with a range of problems which include confusion and behavioural changes. If uncorrected, convulsions and even unconsciousness may occasionally occur.[9] Insulin-treated diabetics regularly measure their own blood glucose levels.[10] If the early symptoms of hypoglycaemia appear or the blood glucose measurements start to fall, hypoglycaemia can be averted by eating sugary foods.[11] In this way, many insulin-treated diabetics can manage their glycaemic state and avoid serious hypoglycaemia.[12] While most insulin-treated diabetics experience warning symptoms of hypoglycaemia, a significant group have poor or no warning symptoms.[13] The longer the individual has been on insulin treatment, the more common it is to have diminished awareness of the onset of hypoglycaemia.[14]

9. A major concern and potential hazard is that an insulin-treated diabetic driver may become hypoglycaemic whilst driving and collapse at the wheel. This is of particular concern in individuals prone to becoming hypoglycaemic without awareness of its onset. The risk of hypoglycaemia and the resultant possibility of altered consciousness while driving is the basis for arrangements restricting the driving entitlements of insulin-treated diabetics.[15]

10. A further concern for diabetic drivers is that diabetes may affect eyesight. Whilst eyesight is an important aspect of fitness to drive in diabetics, in this case study we have restricted ourselves to considering only the issue of hypoglycaemia as a result of insulin treatment and not the wider implications of diabetes.

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[6] Ev. p. 1.

[7] Wellcome News, Supplement 3: *Research Directions in Diabetes*, p. 2, The Wellcome Trust, 1999.

[8] Hypoglycaemia is a state of lower than normal concentrations of glucose in the blood.

[9] Q. 69.

[10] Q. 33.

[11] The early warning symptoms of hypoglycaemia include sweating, shaking, tremor, palpitations and hunger. *See* Ev. p. 12.

[12] Q. 33.

[13] Q. 69

[14] Q. 70.

[15] Ev. p. 42.

## CHAPTER TWO: INSULIN TREATMENT AND DRIVING

### Group I Vehicles—Cars and Motorcycles

11. In the UK, there are around 100,000 insulin-treated diabetic drivers.[16] On passing a driving test for a Group I vehicle (cars and motorcycles), licences are issued which are normally valid until the age of 70.[17] Insulin-treated drivers, however, are required to renew their driving licences every 3 years, or more frequently depending on their health.[18] The Driver and Vehicle Licencing Agency (DVLA) requires all insulin-treated licence applicants (for both new licences and renewals) to complete a self-assessment form providing information on the frequency, severity and awareness of onset of hypoglycaemia. The form also provides consent for the DVLA to contact the applicant's general practitioner or consultant physician. Trained, but non-medical, DVLA staff review the self-assessment form and decide whether or not to issue (or renew) a licence on criteria set down by the Honorary Advisory Panel on Driving and Diabetes Mellitus.[19] Difficult or borderline cases are referred to DVLA medical advisers who may refer them on to the Honorary Advisory Panel.[20]

12. The main criterion for issuing or renewing licences for insulin-treated diabetics concerns the warning of incipient hypoglycaemia. The applicant "must demonstrate satisfactory control, recognise warning symptoms of hypoglycaemia and meet required visual standards".[21] The Chairman of the Honorary Advisory Panel, Dr Peter Watkins, Consultant Physician at King's College Hospital, London, told us that any insulin-treated diabetic who suffers loss of awareness of the onset of hypoglycaemia should be barred from driving any vehicle.[22]

### Group II Vehicles—Lorries, Minibuses, Coaches and Buses

13. Group II vehicles are the heavier road vehicles including the medium-sized vehicles (small lorries and minibuses) and the largest vehicles (large lorries, coaches and buses).[23] Until implementation of the First European Directive on Driving Licences in 1991, insulin-treated diabetics were allowed to drive Group II vehicles.[24] Those that held licences at that time have been allowed to renew their licences every three years since then, dependent upon a satisfactory medical examination. These so-called "grandfather rights" now apply to only 200 or so individuals.[25]

14. Insulin-treated diabetics are not allowed to apply for new licences to drive Group II vehicles. The stated rationale for this rule is that these vehicles are heavier and the consequences of an accident in these vehicles, in terms of injury, loss of life or damage to property is much greater than for the smaller Group I vehicles (cars and motorcycles).[26] It is a similar rationale that debars insulin-treated diabetics from serving as airline pilots or main-line train drivers.[27]

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[16] Ev. p. 42.

[17] Group I vehicles include motorcycles (category A) and cars with up to 8 seats and vans up to 3.5 tonnes (category B).

[18] Ev. p. 42.

[19] Hereafter "*The Honorary Advisory Panel*".

[20] Ev. p. 43.

[21] *At A Glance Guide to the Current Medical Standards of Fitness to Drive*, DVLA, March 1998.

[22] Ev. p. 33.

[23] Group II vehicles include small lorries between 3.5 and 7.5 tonnes (category C1), minibuses with 9–16 passenger seats (category D1), lorries over 7.5 tonnes (category C) and coaches and buses with 17 or more passenger seats (category D).

[24] Ev. p. 43.

[25] Ev. p. 43.

[26] Ev. p. 42. *See also* Ev. p. 33.

[27] Ev. p. 33.

## THE EUROPEAN COMMUNITY SECOND DIRECTIVE ON DRIVING LICENCES, 1991

15. The bar on insulin-treated diabetics driving all heavy vehicles is a recent development which has arisen from an attempt to harmonise driver licensing regulations across the European Union (EU). The Second Directive on Driving Licences, which was adopted in 1991, was implemented in the UK with effect from 1997 through the Driving Licences (Community Driving Licences) Regulations 1996 and the Motor Vehicles (Driving Licences) Regulations 1996.[28] In the UK, this directive brought small lorries and minibuses into Group II for the first time.[29] From 1997, new drivers were not allowed to drive such vehicles without passing the appropriate additional driving test. From 1998, existing licence holders lost their entitlement to drive small lorries and minibuses on expiry of their current licence, normally at the age of 70.[30] For insulin-treated drivers, however, this meant that they lost their entitlement to drive medium-sized vehicles at the expiry of their current 3 year licence. The Second Directive also had the effect of applying the more rigorous Group II health standards to minibuses and small lorries for the first time and so insulin-treated drivers were no longer entitled to apply for licences for these vehicles, even if they had the driving skills required to pass the additional test. Grandfather rights were not granted in the Second Directive.[31] Dr Watkins told us that there was no scientific evidence to support the decision to extend the medical rules to apply to medium-sized vehicles.[32]

16. The Second Directive had the effect of reducing the driving rights of insulin-treated diabetics, some of whom have suffered loss of employment as a result.[33] For example, we have received evidence from Mr Stephen Bretel who told us that despite good glycaemic control he has lost employment as an outdoor education instructor because his right to drive minibuses has been withdrawn.[34] The British Diabetic Association (BDA), the main representative body for people with diabetes, has provided us with a number of other examples of individuals suffering hardship as a result of the UK's interpretation and implementation of this Directive, notwithstanding some of the exceptions introduced in the UK since (see paragraphs 17–21).[35] Further, the Federation of Small Businesses points out that the livelihoods of people with small businesses could be put at risk if they or a key driving employee were to be diagnosed as needing insulin treatment.[36]

## EXCEPTIONS

17. There is a number of exceptions to the outright ban on insulin-treated diabetics driving Group II vehicles.

### *Minibuses*

18. Some parts of the large UK voluntary sector are heavily dependent on voluntary minibus drivers. Full implementation of the Second Directive, requiring a higher level occupational driving test for minibuses, might therefore have adversely affected them.[37] For this reason, the UK negotiated and secured an exception to the Second Directive which allowed all licensed UK car drivers to drive minibuses on a voluntary, unpaid basis. Thus, not only was an exception made for voluntary minibus drivers but the health standard required for them was lowered from that appropriate to Group II drivers to that for Group I drivers.

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[28] Ev. p. 44.
[29] Ev. p. 44.
[30] Ev. p. 42.
[31] Ev. p. 42.
[32] Q. 97.
[33] Ev. p. 1; Q. 23.
[34] Ev. p. 58.
[35] Ev. p. 6.
[36] Ev. p. 60.
[37] QQ. 152 and 154.

### *Small Lorries*

19. The ban on insulin-treated diabetic drivers driving small lorries was applied to each individual as their licences came up for (three-yearly) renewal. Following advice from the Honorary Advisory Panel and wider consultation, the Government allowed a provision in the Directive for "very exceptional cases" to be applied to insulin-treated vocational drivers of small lorries who hold Group I licences, to allow them to continue driving small lorries if they needed to do so for work, subject to medical checks.[38] One medical assessment is carried out by the applicant's doctor and a second by a hospital diabetes consultant and the results are submitted to the DVLA for a final licensing decision.[39] The medical expenses are met by the applicant.[40]

20. The Government also decided that such drivers must have driven small lorries for a minimum of four hours each day for three out of each seven days and for 12 months in the last 24 months.[41] Under these criteria, only 250 licences have been issued out of 1,200 applicants.[42] These minimum driving time criteria were introduced without any consultation and the Minister conceded that this "was a mistake".[43]

## ARRANGEMENTS IN OTHER COUNTRIES

21. Other EU Member States have always included medium-sized vehicles in Group II and so the Second Directive has had little effect on them. For Group II vehicles, however, there is wide variation in practice across the EU in respect of licensing insulin-treated diabetics.[44] Some countries do award new Group II licences to insulin-treated diabetics in certain circumstances. Table 1 shows the position at the beginning of 1999 as presented by the DETR.[45]

| EU member states licensing insulin-treated diabetics to drive Group II vehicles. | | |
|---|---|---|
| | **New Group II Licences** | **Group II licence renewal** |
| **Austria** | Not issued | In exceptional cases only |
| **Belgium** | Special medical procedure | Special medical procedure |
| **Denmark** | Special medical procedure | Special medical procedure |
| **Finland** | Not issued | In exceptional cases only |
| **France** | Not issued | In exceptional cases only |
| **Germany** | Special medical procedure | Special medical procedure |
| **Ireland** | Not issued | |
| **Luxembourg** | In exceptional cases only | In exceptional cases only |
| **Netherlands** | Special medical procedure | Special medical procedure |
| **Portugal** | Not issued | In exceptional cases only |
| **Spain** | In exceptional cases only | In exceptional cases only |
| **Sweden** | Licences issued for lorries | |
| **UK** | Not issued | In exceptional cases only |

**Table 1**
Source: DETR, Ev p. 47.

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[38] Ev. p. 45.
[39] Ev. p. 70.
[40] Ev. p. 70.
[41] Ev. p. 3.
[42] Ev. p. 45.
[43] Q. 149.
[44] Q. 153.
[45] Ev. p. 47.

22. As the BDA pointed out, some other countries are less stringent, allowing insulin-treated individuals to drive vehicles which insulin-treated drivers in the UK may not drive.[46] The BDA also suggests that some EU countries have adopted a more liberal interpretation of the Directive's "very exceptional cases" provisions than that applied in the UK.[47] The DETR told us that the European Commission has "deprecated the approaches which appear to go beyond 'only in very exceptional cases' — notably those of the Benelux countries and Denmark".[48] **The UK's position on exceptional cases for renewing existing professional insulin-treated drivers' entitlements was to some extent based on the view of the Honorary Advisory Panel. That panel's view, however, was influenced by DETR advice that other member states were applying a ban. The DETR now concedes that "that information turned out not to be accurate".[49] We recommend that the Government refers this matter back to the Honorary Advisory Panel for further consideration based on an understanding of practice in other EU countries.**

### THE ANOMALOUS NATURE OF THE DRIVING RULES

23. Insulin-treated diabetics can only drive small lorries if they are professional drivers but can only drive minibuses on a voluntary basis. As Dr Watkins, Dr Frier and the Royal Society of Edinburgh all agree, the anomaly for minibuses is illogical and makes enforcement difficult.[50] Such drivers are no safer because they are not being paid. The minibus exception for the UK was negotiated for the sake of the voluntary sector. **We find the rules for medium-sized vehicles as they apply to insulin-treated drivers illogical and inconsistent. We see no reason why the exception for voluntary drivers of minibuses should be extended to those who do not meet the required medical standards for driving larger vehicles.**

24. Presumably, the exception for professional drivers of small lorries was allowed to avoid hardship for insulin-treated drivers who depended on driving these vehicles for their livelihoods. The criterion used, however, appears to be based upon how much time the driver spends behind the wheel rather than the degree of hardship which would be caused by the loss of driving entitlement. The DETR told us that this was an "administrative decision for fulfilling the criteria which had been agreed as a concession from Europe" and that applicants had to have "sufficient" and "recent" driving experience in small lorries.[51] **We consider that the exception for insulin-treated professional drivers of small lorries has been applied in an unacceptably arbitrary manner. We recommend that the overriding criterion which should be applied in determining whether or not any diabetic driver should obtain a Group II licence should be the risk of the driver being unaware of the onset of hypoglycaemia.**

### Compliance with the Medical Rules for Licensing

25. The DETR estimates that, of all road accidents resulting from a collapse at the wheel (for a variety of medical reasons including diabetes), 76% of the drivers had not previously declared any medical condition to the DVLA.[52] Dr Frier, a member of the Honorary Advisory Panel estimated that 40% of insulin-treated drivers had not declared their condition to the DVLA.[53] We are greatly concerned that so many individuals with declarable conditions are failing to declare their conditions to the DVLA. This must constitute a serious threat to road safety. We note that the DVLA is planning a publicity campaign among the public and health professionals to highlight both the need and the legal requirement to notify them of medical conditions which may affect driving.[54] **We welcome the planned campaign to raise awareness of the need to declare medical conditions which may affect driving.**

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[46] Ev. p. 7; *See also* Ev. p. 60.

[47] The BDA also provided us with examples from non-EU countries such as New Zealand, Canada and the USA where more liberal approaches are used for the licensing of insulin-treated drivers of commercial vehicles. *See* Ev. p. 22.

[48] Ev. p. 48.

[49] Ev. p. 46.

[50] QQ 113 and Q.116; Ev. p. 61.

[51] Q. 150.

[52] Ev. p. 70.

[53] Q. 74.

[54] Q. 142.

## CHAPTER THREE: THE SCIENTIFIC ADVISORY SYSTEM

### The Honorary Advisory Panel on Driving and Diabetes Mellitus

26. The Minister told us that the Government's source of scientific advice on the safety of driving with diabetes is the Honorary Advisory Panel.[55] The Panel is appointed by the Secretary of State.[56] It is tasked with advising the DETR, through the DVLA, on licensing policy regarding people with diabetes, based on an assessment of the risk of a debilitating episode at the wheel.[57] It is one of six panels advising on the safety of driving with various medical conditions. It has no formal terms of reference. We can see no justification for the absence of formal terms of reference for the Honorary Advisory Panel. The BDA points out that this lack of terms of reference makes it difficult to understand the full extent of the Panel's responsibilities.[58] **We recommend that clear terms of reference be drawn up for the Honorary Advisory Panel, setting out precisely its role in advising Ministers, the limits on the areas it should advise upon and the split between Panel, official and Ministerial responsibility.**

#### MEMBERSHIP

*Expertise*

27. In any examination of a scientific advisory process, the scientific expertise of those providing the advice is a central issue. The Honorary Advisory Panel needs to assess the likelihood of traffic accidents as a result of hypoglycaemia in a range of patients with different symptoms and to set appropriate standards. This requires a high standard of expertise and the Honorary Advisory Panel needs a substantial base of clinical experience in diabetes if it is to perform effectively and retain public confidence.[59] Its membership consists of six consultant physicians specialising in diabetes and a consultant in occupational medicine.[60] The BDA told us that the Honorary Advisory Panel "is made up of diabetes specialists, well respected in their field".[61] **The current members of the Honorary Advisory Panel have the necessary expertise and experience in diabetes and insulin-induced hypoglycaemia.**

28. We are concerned, however, that the Panel may be asked to provide advice on, or to take into consideration, issues which are outside its areas of expertise in diabetes. The Panel's Chairman, Dr Watkins, told us that the Panel would find an expert on road accident statistics "extremely valuable".[62] The BDA told us that policy decisions in this area "must be made in consultation with a wide variety of experts, including, for example, traffic, accident and road user experts".[63] The Chairmen of all of the Honorary Medical Advisory Panels recently met and discussed the value of having such expertise on a panel and "were very receptive to the idea and are considering it".[64] We note that the Honorary Advisory Panel on Driving and Disorders of the Nervous System already has a member who is a senior statistician at the Institute of Public Health at Cambridge and see no reason why this principle should not be extended to the Honorary Advisory Panel on Driving and Diabetes Mellitus. **We recommend that the Government appoints an expert on road traffic accident statistics to the Honorary Advisory Panel on Driving and Diabetes Mellitus and considers similar appointments to the other Honorary Medical Advisory Panels.**

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[55] Q. 126.
[56] Ev. p. 42.
[57] Ev. pp. 43 and 69.
[58] Ev. p. 9.
[59] Q. 107.
[60] Ev. pp. 49–50.
[61] Ev. p. 9; *See also* Q. 25.
[62] Q. 108.
[63] Ev. p. 2.
[64] Q. 160.

### *Lay Membership*

29. We have previously stressed the importance of lay membership on scientific advisory bodies.[65] Lay members can challenge the assumptions of a scientific advisory committee, scrutinise its processes and witness the quality and objectivity of scientific decision-making, serving both to ensure the maintenance of high-quality scientific advice and to provide public confidence. The Government's Chief Scientific Adviser has set out the need "to involve at least some experts from other, not necessarily scientific, disciplines, to ensure that the evidence is subjected to a sufficiently questioning review from a wide ranging set of viewpoints".[66] We note that the Honorary Advisory Panel on Driving and Diabetes Mellitus has no lay members; nor do any of the other Honorary Medical Advisory Panels. The Panel's Chairman told us that, while a lay member might not be able to contribute to the technical side of the Panel's discussions, such a member could make a valuable contribution "in terms of common sense".[67] The BDA has also pointed out the absence of lay members on this Panel and suggested that it should have two lay members because a single lay member might find a strongly scientific panel intimidating.[68] **The absence of lay membership on the Honorary Advisory Panel is unsatisfactory. We recommend that the Government appoints two lay members to this Panel and considers similar action in respect of the other Honorary Medical Advisory Panels.**[69]

30. The BDA proposed that one of the Panel's lay members should be a diabetic, arguing that people with diabetes can bring a wider experience and the views of diabetics to the Panel.[70] As we have argued before, we do not believe that membership of scientific advisory bodies should be representative in nature.[71] The task of providing scientific advice is a specialist one and membership of committees should be made up of those best placed to provide the specialist advice. Both the Honorary Advisory Panel and the BDA agree that the BDA should not have its own representative on the Panel.[72] We recognise, however, that understanding between the Honorary Advisory Panel and diabetics, through their main representative body, the BDA, could be improved. Therefore, **we recommend that the Government and the BDA jointly identify an insulin-treated diabetic to attend meetings of the Honorary Advisory Panel as a non-voting member. While such an individual should not be a formal member of the Panel, he or she should have full access to Panel papers and be invited to participate fully in discussions.**

### *Turnover*

31. The Honorary Advisory Panel was established in 1983.[73] Two of the current seven members have been on the Panel since 1985 and one since 1989.[74] Appointments are open-ended and there is currently no provision to change membership as a matter of routine, a practice which conflicts with the rules set down by the Commissioner for Public Appointments.[75] At a recent meeting, the Chairs of the Honorary Medical Advisory Panels agreed that appointments

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[65] *See* First Report, Session 1998-99, *Scientific Advisory System: Genetically Modified Foods*, HC 286, para 53. *See also* Third Report, Session 1998-99, *Scientific Advisory System: Mobile Phones and Health*, HC 489 para 33.

[66] *The Use of Scientific Advice in Policy Making,* Office of Science and Technology, March 1997, para 6.iv.

[67] Q. 120.

[68] Q. 51; *See also* Ev. p. 9.

[69] This is in line with our previous recommendations that lay members should make up a fifth of the membership of scientific advisory bodies. *See* First Report, Session 1998-99, *Scientific Advisory System: Genetically Modified Foods*, HC 286, para 53; Third Report, Session 1998-99, *Scientific Advisory System: Mobile Phones and Health*, HC 489, para 33.

[70] QQ. 52–53; Ev. p. 9.

[71] *See* First Report, Session 1998-99, *Scientific Advisory System: Genetically Modified Foods*, HC 286, para 47.

[72] QQ. 32 and 109.

[73] Ev. p. 43.

[74] Ev. p. 49.

[75] Q. 161; The Commissioner for Public Appointments recommends that appointments should be for between 3-5 years with a maximum period of 10 consecutive years and that the duration of the appointments should be staggered when a number of appointments to one body are being made to avoid future difficulties of losing a large number of board members at any one time. *See The Commissioner For Public Appointments' Guidance on Appointments to Public Bodies,* July 1998, para 3.68.

to panels should be for a fixed term, and be renewable only once.[76] This view is also endorsed by the BDA.[77] The Minister told us that a policy of five-year appointments, renewable only once, would be implemented.[78] **The arrangements for appointment of members to Honorary Medical Advisory Panels are unsatisfactory. We recommend that the Government establish a fixed term of appointment of no longer than five years, which should be renewable only once. Such a policy, although necessary to comply with the rules of the Commissioner for Public Appointments, should be implemented gradually so that continuity is maintained and to ensure that there is no large change in the Panels' membership at any one time.**

### TRANSPARENCY

32. If the public is to have confidence in policy, the scientific basis of that policy must be open to scrutiny by interested parties. The operation of the Honorary Advisory Panel has, however, been criticised for a lack of openness. The BDA pointed out that it met the Honorary Advisory Panel for the first time in September 1999 and remains unclear about the way in which it operates.[79] Decisions and recommendations of this Panel have important implications for a large number of insulin-treated diabetics with regard to their freedom to drive. Any suspicion that its affairs are not being conducted properly will undermine public confidence in the process which may, in turn, lead to further non-compliance with the licensing rules. We note for example the BDA's fear that the Panel "may simply be asked to ratify positions or advice put to them by civil servants".[80] **We recommend that the Honorary Advisory Panel publishes an annual report and, shortly afterwards, hold an annual meeting with the BDA and other interested parties to discuss matters of common interest and to explain any complex recommendations made.**

33. None of the Panel's papers are made public.[81] Publication of agendas and minutes would increase significantly the transparency of the Panel's operation and help to explain to the public the scientific basis for most of its recommendations and decisions. It would also further enhance public confidence in the scientific advisory system. The Minister told us that there may be problems with privacy regarding publication of the Panel's agendas and minutes as it deals with individual cases. We believe that this problem can be easily solved by publication of agendas and minutes with individual cases made anonymous in the published versions, as is commonly the practice in medical literature. **We recommend that the Honorary Advisory Panel's agendas are published in advance of meetings and that minutes be published shortly after meetings, with the privacy of any individuals discussed suitably protected.**

### ASSESSING RISK

34. The limits which are set around the areas of advice for which the Honorary Advisory Panel is responsible are unclear. The Chairman told us that his Panel has consistently advised against the licensing of insulin-treated diabetics to drive the largest vehicles, lorries and buses, on the grounds that these vehicles have greater potential for harm in an accident.[82] He also told us that the Panel was "always concerned" about extending the more stringent medical rules for Group II to apply to medium-sized vehicles.[83] Whilst the members of this Panel are clearly competent to judge the likelihood of hypoglycaemia in insulin-treated diabetics exhibiting certain sets of symptoms, we are not clear how they can make the judgement as to how that likelihood translates into a risk of a road traffic accident and whether that risk is acceptable in the various different vehicle categories. The Minister told us that in this area "final responsibility rests with

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[76] Q. 111.
[77] Ev. p. 9.
[78] Q. 161.
[79] Q. 44.
[80] Ev. p. 9.
[81] QQ. 164 and 46.
[82] Ev. p. 33.
[83] Ev. p. 33.

Ministers because it comes through legislation and regulation" while risk assessment rests with the DVLA and the Honorary Advisory Panel.[84]

35. Dr Watkins told us that the acceptable probability of an accident in a large vehicle has been set at a lower level than that acceptable for an accident in a small one.[85] In common with the BDA, we have not been able to identify any quantification of acceptable risk levels; nor is it clear who is responsible for setting them.[86] Ministers are the ultimate guardians of public safety and rights and must take the responsibility for deciding on what levels of risk are acceptable, in this case striking a balance between road safety and the right to drive. **We recommend that the Government makes explicit the risk basis for road safety policy in respect of licensing of individuals with medical conditions which potentially affect fitness to drive.**

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[84] Q. 125.

[85] Ev. p. 33. *See also, At a Glance Guide to the Current Medical Standards of Fitness to Drive*, DVLA, 1998.

[86] Q. 6.

## CHAPTER FOUR: EVIDENCE BASED POLICY

### Insulin Treatment and Road Safety

36. The decision to remove an individual's right to drive must be balanced against the risk to road safety (see paragraph 3). This decision should be based on clear evidence. Some insulin-treated diabetics are poorly controlled and are more likely to have a hypoglycaemic episode while driving, which in turn may cause an accident.[87] Other individuals are well-controlled, never having experienced unwarned hypoglycaemia and arguably pose no more of a risk to road safety than non-diabetic drivers. There is, however, very little evidence or scientific data to determine just how much of a road safety risk these different individuals represent, and it is worth noting that there are no detailed actuarial statistics which can support higher motor insurance premiums for insulin-treated diabetics.[88] Further, the Association of British Insurers states that it is likely to be some time before any meaningful statistics become available.[89] The BDA commissioned a review of the available evidence which concluded that there was little evidence to suggest that insulin-treated diabetics are at any greater risk of road accidents than other members of the driving public.[90]

37. The validity of using the statistics and studies cited by the BDA has been questioned by Dr Watkins who pointed out weaknesses in the data and he also commented that statistics may be distorted by many licensed diabetic drivers who regulate their own driving as a result of hypoglycaemic experiences.[91] Dr Watkins also pointed out that accidents, some fatal, occur as a result of hypoglycaemia although the number of such accidents is not known.[92] Lord Whitty told us that it was "fairly clearly established" that an insulin-treated diabetic has a 10% chance of a hypoglycaemic episode in any one year.[93] He also told us that annually there are around 120 police reports of collapse at the wheel as a result of hypoglycaemia and that "that is probably a serious underestimate".[94]

38. The usefulness of these statistics, however, is compromised. They take no account of whether the individual drivers concerned have been assessed as having well- or poorly-controlled blood sugar. Interpretation is also complicated by the estimated low level of compliance with the requirement to declare medical conditions to the DVLA.[95] It is clear then that there is little understanding of how different insulin-treated individuals can be judged to be a higher risk on the road than the average driver. Nor can it be said to what extent such individuals represent an unacceptable risk when driving different heavier classes of vehicles. Without robust scientific evidence on the relationship between insulin treatment, control of hypoglycaemia and road safety, appropriate licensing restrictions are impossible to define. The DVLA has recently initiated a project to analyse the available figures — the first time it has attempted to do so.[96] **The DETR states, however, that independent UK evidence is unnecessary because the present policy and practices are derived from obligations to adhere to European legislation based on "long-standing expert assessment of the dangers associated with the driving of larger vehicles by insulin-treated diabetics".[97] This assessment does not appear to be supported by any evidence. We recommend that the evidence basis for such expert assessment should be made publicly available.**

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[87] Ev. p. 33.
[88] Q. 119; Ev. p.1; Ev. p. 57.
[89] Ev. p. 57.
[90] *See* Ev. p. 4; Ev. pp. 11–20.
[91] Ev. p. 33.
[92] Ev. p. 3; *See also* Q. 71.
[93] Q. 140.
[94] Q. 124.
[95] Ev. p. 70.
[96] QQ. 71 and 145.
[97] Ev. p. 48.

## The DETR Fitness to Drive Research Programme

39. The DETR has recently invited tenders for managing a new *Fitness to Drive Research Programme.*[98] This programme will run over four years and is intended to help the DETR "enhance its understanding of driving safety risks associated with medical conditions in order to make safe, consistent and fair decisions on licensing" and to "keep abreast of advances in medicine in order to contribute to discussions which may lead to changes in the European Law".[99] The programme, at an estimated cost of £430k, will consider: incremental driving safety risks with medical conditions; methods for assessing visual fields; links between hypoglycaemia in insulin-treated diabetes and driving accidents; psychiatric conditions and driving accidents; the attitudes of health professionals towards medical aspects of road safety; and the analytical use of DVLA medical data.[100] The DETR estimates that the project looking at insulin-treated diabetes and driving will be funded at a total cost of around £80k over two years.[101] This is the first time the DETR has supported research in this area.[102] This research programme was advertised stating that the evidence on which standards are now based "is variable in quality and has not been reviewed using the best available methodology".[103] The DETR told us that "the evidence is wanting and that is what the research is actually targeted at".[104] We agree that, given the near absence of evidence supporting the current policy for licensing 100,000 insulin-treated drivers, a research programme is both necessary and welcome. The breadth of the *Fitness to Drive Research Programme* is, however, such that the funding available will be too thinly spread and we consider that it is over-optimistic to expect a single research programme of £40k per annum for two years to be sufficient to provide a scientific basis for policy in an area where, in terms either of road safety or the right to drive, the costs of getting the policy wrong, could be much greater. **We recommend that the scope and depth of the research programme should be enhanced and adequately funded.**

## The BDA model for individual assessment

40. In the absence of robust evidence to support the current policy of not licensing any insulin-treated drivers for heavy vehicles, the BDA proposes that licencing for such vehicles should be based on a professional assessment of individual drivers' ability to control blood glucose levels.[105] For cars and motorcycles, such an arrangement already exists. Drivers fill in a medical form and send it to the DVLA where an assessment is made of fitness to drive.[106] For Group II vehicles, principally medium-sized vehicles, the BDA proposes that a similar arrangement could be applied but with more rigorous medical criteria, based on professional medical examination rather than self-assessment.[107] Individual assessment with more stringent medical criteria is currently used as part of the "exceptional case" applications process for renewal of entitlement to drive small lorries.

41. Dr Watkins told us that such a scheme of individual assessment was scientifically feasible but he expressed concerns about the associated logistics.[108] We believe that the proposal has its merits although, in implementation, care would have to be taken to ensure compliance with the Second European Directive on Driving Licences. The BDA suggests that there is a risk that the present blanket ban may encourage drivers to conceal their insulin-treatment for fear of losing employment whereas individual assessment would at least offer some hope that they can meet the required criteria and the assurance that the denial of a licence was based on criteria relevant

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[98] Ev. p. 62.
[99] Ev. p. 62.
[100] Ev. pp. 64–69.
[101] QQ. 129–133.
[102] Q. 130.
[103] DETR Fitness to Drive Research Programme Advertisement, *Research Fortnight*, *See* Appendix I.
[104] Q. 141.
[105] Ev. p. 3.
[106] Ev. p. 70.
[107] Ev. p. 4.
[108] Q. 104.

to the individual.[109] **We recommend that the Government reviews policy in the area of licensing procedures for insulin-treated diabetic drivers of Group II vehicles including an analysis of the feasibility of implementing the BDA proposals for individual assessment.**

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[109] Ev. p. 6.

## CHAPTER FIVE: CONCLUSIONS

42. Striking a balance between the public's need and desire for improved road safety and the individual's right to drive is a difficult judgement which rightly falls to Ministers to make. Ministers need good quality scientific advice in order to reach a fair and appropriate decision. The current position for insulin-treated drivers, particularly for heavy, Group II, vehicles is not supported by evidence and includes policy anomalies which have caused hardship for some individuals. In the past, Governments appear to have accepted and implemented the health aspects of European Directives on Driving Licences on the basis of minimal supporting evidence. For the first time the Government is now embarking on a research programme to generate evidence in support of policy in this area and this is most welcome. We are, however, concerned that this research programme may be too small to deliver sufficient evidence on which to base new policy or EU negotiations on licensing in the future.

43. We have found in this case study that the members of the Honorary Advisory Panel are well-qualified to advise on the nature and risks of hypoglycaemia experienced by insulin-treated drivers. However, the Panel needs to be given clear terms of reference, and individual members should not remain for more than ten years. To enhance public confidence the Panel's proceedings need to be more open; consultations with interested organisations like the BDA need to improve; and membership of the Panel should be augmented by the inclusion of an expert in road accident statistics and two lay members.

44. It is astonishing that statistics on the incidence of road accidents involving diabetic drivers have not been regularly compiled in the past. The Government's immediate intention to remedy the deficiency is to be welcomed. However, we question the adequacy of the scale of the exercise now proposed at £40,000 per annum over two years and recommend that the scope and depth of the exercise now planned should be enhanced. Moreover, we believe that arrangements should be made to keep such statistics up to date once they are established.

45. Implementing our recommendations will cost little but they will put the driving rules for insulin-treated diabetics on a firm foundation of evidence and make clear that the responsibility for deciding acceptable levels of risk lies with the Minister. Our recommendations would also avoid the curious anomalies we have identified which undermine confidence in the licensing rules. We are pleased to note that a number of the changes we propose are already being discussed in the DETR.

46. Although we have only examined one of several DETR panels advising on the medical risks associated with driving, it is likely that some or all of our recommendations apply to all such Panels serving the DETR. We therefore believe that the applicability of our recommendations to all Honorary Medical Advisory Panels should be considered by the DETR.

## GLOSSARY

| | |
|---|---|
| BDA | British Diabetic Association |
| DETR | Department of the Environment, Transport and the Regions |
| DVLA | Driver and Vehicle Licencing Agency |
| EU | European Union |

# APPENDIX 1

## The DETR's Fitness to Drive Research Programme Advertisement:

**DETR**

*Department of the Environment, Transport and the Regions*

### FITNESS TO DRIVE RESEARCH PROGRAMME

**The Department for Environment Transport and the Regions (DETR) request the expressions of interest to tender for the management of the research programme outlined below.**

A programme of review and research is to be undertaken over the next four years to improve the scientific basis for setting standards on medical aspects of fitness to drive in the UK. As standards contribute to road safety but also prevent many people from holding driving licences they need to be evidence based and relate to estimates of risk whenever possible.

The evidence on which these standards are now based is variable in quality and has not been reviewed using the best available methodology. The programme will include both systematic reviews of common medical risks and research projects to fill known knowledge gaps and those identified by the reviews. Major subject areas are: cardiovascular disease; diabetes; visual performance, and neurological conditions such as epilepsy, stroke and dementia.

A contractor is required to manage this programme on behalf of DETR. They should be competent in UK public sector procedures for research management and understand the subject area in sufficient detail to liaise directly with reviewers and researchers on the scientific quality assurance arrangements for projects. The contractor will be accountable to the Chief Medical Adviser (Transport Safety) who will be the DETR project officer.

The following information must be forwarded with your expression of interest.

- Whether any of the circumstances described in Article 29 (a-g) of Directive 92/50/EEC (Regulation 14 of UK SI 1993 No 3328) including,but not limited to, environmental issues, apply:
- full name and address:
- a contact name (and status) and telephone number;
- details of the principal services provided in the last three years in connection with the services or any other experience considered relevant;
- details of relevant experience of members of staff;
- length of time trading;
- VAT registration number;
- audited accounts for the last financial year, showing the applicant's overall turnover, and a statement showing turnover in respect of the services to which this contract relates. Where the applicant is part of a group of companies, a copy of the audited accounts of the ultimate holding company for the last financial year are also required.

Any other information that might be useful to those assessing the applicants potential.

Expressions of interest should be sent to Mr T Carter, Chief Medical Adviser, Room 2/14C Great Minster House, 76 Marsham Street, London SW1P 4DR.

## PROCEEDINGS OF THE COMMITTEE RELATING TO THE REPORT

### WEDNESDAY 9 FEBRUARY 2000

Members present:

Dr Michael Clark, in the chair

| | |
|---|---|
| Mr Nigel Beard | Dr Ashok Kumar |
| Mrs Claire Curtis-Thomas | Dr Desmond Turner |
| Dr Ian Gibson | Dr Alan W. Williams |
| Dr Lynne Jones | |

The Committee deliberated.

Draft Report (Scientific Advisory System: Diabetes and Driving Licences), proposed by the Chairman, brought up and read the first time.

*Ordered,* That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 46 read and agreed to.

*Ordered,* That a list of abbreviations be annexed to the Report. — (*The Chairman.*)

*Resolved*, That the Report be the Third Report of the Committee to the House.

*Ordered,* That the Chairman do make the Report to the House.

*Ordered*, That the provisions of Standing Order No. 134 (Select committees (reports)) be applied to the Report.

A paper was ordered to be appended to the Report.

*Ordered,* That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House. — (*The Chairman.*)

Several Papers were ordered to be reported to the House.

[Adjourned till Wednesday 16 February at a quarter to Four o'clock.

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Annexes to Memoranda submitted by the Department of the Environment, Transport and the Regions.

## LIST OF REPORTS

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Second Report: The Year 2000—Computer Compliance (HC 342)

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First Report: The Scientific Advisory System: Genetically Modified Foods (HC 286)

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Printed in the United Kingdom by The Stationery Office Limited
2/00 489841 19585

ISBN 0-10-215200-4

9 780102 152005

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